

REVITALIZING THE PATENT SYSTEM TO INCENTIVIZE PHARMACEUTICAL INNOVATION: THE POTENTIAL OF CLAIMS WITH MEANS-PLUS-FUNCTION CLAUSES

WANLI (LILY) TANG[†]

ABSTRACT

The pharmaceutical industry relies on innovation. However, many innovative firms are cutting their research and development investments and seeing their new product pipelines dry up, due in part to a lack of sufficient patent protection. This Note identifies two major factors that have caused this inadequacy in patent protection. First, pharmaceutical patents are challenged early and often by generic manufacturers, as encouraged by the 1984 Hatch-Waxman Act. Second, the scope of pharmaceutical-patents is sometimes unduly restrained due to limited application of the doctrine of equivalents. Consequently, pharmaceutical patents, especially drug-product patents, are easily designed around and cannot offer the protection necessary for innovative firms to recoup their developmental costs.

This Note argues for a wider application of means-plus-function clauses in pharmaceutical patents as a potential cure for this problem. Means-plus-function claims, although authorized by Congress in the 1952 Patent Act, have not been explored much in the pharmaceutical context. This Note argues that this claiming strategy is not only appropriate but also particularly effective for pharmaceutical patents. Means-plus-function claims would give drug-product patents adequate scope even with the limited use of the doctrine of equivalents and thus would provide the protection necessary for innovative firms to withstand frequent attacks by generic manufacturers. Finally, this Note examines issues anticipated with applying means-plus-function claims to pharmaceutical patents and proposes possible solutions.

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[†] Duke University School of Law, J.D. expected 2013; Duke University, Ph.D. (Molecular Cancer Biology), 2010; Tsinghua University, B.S. (Biological Sciences), 2005. I first thank Professor Arti Rai for her helpful suggestions and guidance on this Note. I also gratefully acknowledge the help from Mr. Gregory Glass for the access to the Paragraph IV website. I would also like to thank Paige Gentry, James Gillenwater, and the rest of the staff of the *Duke Law Journal* for their efforts on this Note. Finally, I want to specially thank Mr. Tom Irving for inspiring me to embark on this project and sharing his insight on this topic.

INTRODUCTION

The United States Constitution endows Congress with the authority to grant inventors time-limited, exclusive rights “[t]o promote the Progress of Science and useful Arts.”¹ Pursuant to this authority, Congress established the patent system to give inventors temporary rights to exclude others from making, using, or selling their inventions or importing them into the United States.² These exclusive rights allow inventors to profit from their ideas, thus providing strong financial incentives for innovation.³

Traditionally, the patent system has been considered successful in promoting innovation in the pharmaceutical industry.⁴ Currently, however, a number of branded pharmaceutical companies face the daunting reality of losing patent coverage on their most lucrative drugs, creating what is known as the “patent cliff” phenomenon.⁵ To be sure, the expiration of such drug patents and the subsequent market entry of generic versions of branded drugs means significant savings for consumers.⁶ This phenomenon, however, also raises concern for the future of new drug development. In the past few years, loss of patent protection has caused sales revenue for

1. U.S. CONST. art. I, § 8, cl. 8.

2. 35 U.S.C. § 154(a)(1) (2006), *amended by* Leahy-Smith America Invents Act, Pub. L. No. 112-29, §§ 3(j), 20(j)(1), 125 Stat. 284, 290, 335 (2011).

3. Kelly A. Gidcumb, *Rethinking the Hatch-Waxman Act: Balancing Both Sides of the Equation*, 6 WAKE FOREST INTELL. PROP. L.J. 23, 26 (2006).

4. See C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613, 613 (2011) (“The pharmaceutical industry is the rare setting in which the patent system works as it is supposed to—or so the story goes.”); Matthew J. Higgins & Stuart J.H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326 SCIENCE 370, 370 (2009) (“[T]here is little debate that [patents] are important for spurring drug innovation.”).

5. See Katie Reid, *Update 4—Novartis To Cut 2,000 Jobs To Save Annual \$200 Mln.*, REUTERS, Oct. 25, 2011, *available at* <http://www.reuters.com/article/2011/10/25/novartis-idUSL5E7LP10G20111025> (“Global drugmakers have cut tens of thousands of jobs ahead of patent expirations on their top-selling products”); Duff Wilson, *Patent Woes Threatening Drug Firms*, N.Y. TIMES, Mar. 7, 2011, at A1 (“This year alone, because of patent expirations, the drug industry will lose control over more than 10 megamedicines whose combined annual sales have neared \$50 billion.”).

6. See, e.g., Ranit Mishori, *Why Are Generic Drugs Cheaper Than Brand-Name Ones?*, WASH. POST (July 11, 2011), http://articles.washingtonpost.com/2011-07-11/national/35267296_1_generic-drugs-manufacturers-of-brand-name-drugs-pharmaceutical-companies (“Generic makers don’t face the same costs as manufacturers of brand-name drugs. . . . [T]he brand-name maker often invented the drug, a process that can cost hundreds of millions of dollars. . . . [The brand-name maker’s] investment also includes advertising For a generic manufacturer, no such investment is required—not in development and not in marketing.”).

innovative firms to plummet, compelling them to restructure to survive financially.⁷ As a part of this restructuring, many firms have heavily cut their investments in research and development (R&D) for new products.⁸

Widespread reduction in R&D investment is particularly alarming because the pharmaceutical industry is very research intensive and heavily depends on product innovation.⁹ Over the years, developing a new drug has become increasingly expensive, time-consuming, and risky.¹⁰ On average, developing a new medicine and securing Food and Drug Administration (FDA) approval requires screening between five and ten thousand compounds.¹¹ This process takes on average ten to fifteen years and costs \$1.3 billion.¹² Indeed, with shrinking R&D investment and increasingly costly drug development, a number of branded pharmaceutical firms have experienced a drying up of their new-product pipelines in the past

7. See, e.g., *Drugmaker AstraZeneca To Cut 1,150 U.S. Employees*, USA TODAY (Dec. 7, 2011), <http://www.usatoday.com/money/industries/health/drugs/story/2011-12-07/Astra-zeneca-layoffs/51708132/1> (“Drugmaker AstraZeneca will cut roughly 24% of its U.S. sales force in an effort to curb costs, part of a company-wide restructuring announced in 2010.”).

8. See, e.g., Daniel Cressey, *Pfizer Slashes R&D*, 470 NATURE 154, 154 (2011) (“With key patents about to expire, Pfizer, the world’s largest pharmaceutical company in terms of sales, unveiled plans to slash its research and development (R&D) spending by billions and cut thousands of jobs.”); Sten Stovall, *R&D Cuts Curb Brain-Drug Pipeline*, WALL ST. J. (Mar. 27, 2011), <http://online.wsj.com/article/SB10001424052748704474804576222463927753954.html> (“Many companies . . . have recently scaled back their research into how the brain works and affects behavior.”); Lori Valigra, *Biotech Companies Cut R&D Spending, Maintain Cash Reserves*, BDO Study Says, MASS HIGH TECH (July 29, 2011, 2:19 PM EDT), <http://www.masshightech.com/stories/2011/07/25/daily54-Biotech-companies-cut-RD-spending-maintain-cash-reserves-BDO-study-says.html> (“R&D efforts may be a mission critical activity for biotech companies, but a new report says public biotechs have cut spending for the second straight year . . .”).

9. See CONG. BUDGET OFFICE, PUB. NO. 2589, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 9 (2006), available at <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf> (stating that the percentage of total sales revenue that is invested in R&D at an average pharmaceutical company is five times higher than that at the average manufacturing firm).

10. PHARM. RESEARCH & MFRS. OF AM., PHARMACEUTICAL INDUSTRY 2011 PROFILE 10 (2011), available at http://catalyst.phrma.org/wp-content/uploads/fromPhrma/phrma_profile_2011_final.pdf. The major factors behind the increase in the time and cost of new drug development include (1) heightened regulatory requirements regarding trial size and length; and (2) the increased cost of animal testing and conducting clinical trials. Michael Dickson & Jean Paul Gagnon, *Key Factors in the Rising Cost of New Drug Discovery and Development*, 3 NATURE REVIEWS: DRUG DISCOVERY 417, 420, 426 (2004).

11. PHARM. RESEARCH & MFRS. OF AM., *supra* note 10, at 12 fig.4.

12. *Id.* at 10.

decade,¹³ indicating an industry-wide decrease in innovative activities. Because the development of new health-improving or even life-saving drugs relies on pharmaceutical innovation, the potential social loss is difficult to estimate.

Many factors both within and outside of the patent system have contributed to this decline in pharmaceutical innovation.¹⁴ This Note examines the combined effect of two factors within the patent system: the increased generic competition faced by innovative firms and the inadequacy in patent-claim scope¹⁵ for certain pharmaceutical patents. It then explores the unrecognized potential of claims with means-plus-functions clauses (MPF claims) to remedy these problems and revitalize pharmaceutical innovation.

The enactment of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act)¹⁶ has rendered innovative firms more vulnerable to patent challenges and provided great economic incentives for generic manufacturers to initiate these challenges as early as possible.¹⁷ Although intended to strike a balance between innovative firms and generic manufacturers, the Hatch-Waxman Act has been widely criticized for unevenly favoring the generic side of the industry.¹⁸ Since its passage, the United States

13. Lori Valigra, *AstraZeneca, Biogen Look Externally for New Drug Candidates*, MASS HIGH TECH (May 23, 2011, 2:02 PM EDT), <http://www.masshightech.com/stories/2011/05/23/daily10-AstraZeneca-Biogen-look-externally-for-new-drug-candidates.html>.

14. Some factors outside the patent system include the high cost of drug development and inefficiencies in the research community. *See generally* Arti K. Rai, Jerome H. Reichman, Paul F. Uhlir & Colin Crossman, *Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery*, 8 YALE J. HEALTH POL'Y L. & ETHICS 1, 4 (2008) (outlining the major obstacles to producing and developing new small-molecule drugs and proposing a solution); *supra* note 8 and accompanying text.

15. Claims are specific sections in a U.S. patent. Each claim defines the scope of the patented invention—that is, the right protected by the patent document. *See infra* text accompanying notes 97–100.

16. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28, & 35 U.S.C.).

17. *See infra* Part I.C.

18. *See* Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999) (“For those who ask whether Hatch-Waxman was a good deal or a bad deal for the research-based pharmaceutical industry, the most learned response is: It was not a good deal”); Jaclyn L. Miller, Note, *Drug Price Competition and Patent Term Restoration Act: The Elimination of Competition Between Drug Manufacturers*, 5 DEPAUL J. HEALTH CARE L. 91, 103 (2002) (“These benefits [bestowed by the Hatch-Waxman Act] create an unequal playing field that inhibits true competition.”); Mandy Wilson, Note, *Pharmaceutical Patent Protection: More Generic Favored Legislation May Cause Pioneer Drug Companies To Pull the Plug on Innovation*, 90 KY. L.J. 495, 510–11 (2002) (“Although the 1984 Act was considered a compromise at the time it was passed, generic

has seen explosive growth in the generic drug sector,¹⁹ which has led to both significant savings for consumers and to significant profit losses for innovative firms.²⁰ Meanwhile, pharmaceutical patents are challenged more often and earlier in their effective lives than they were prior to the Hatch-Waxman Act.²¹ Whether the current patent system affords innovative firms with an adequate level of protection, then, is highly debatable.

Patent protection has two dimensions: the time period during which exclusive rights last and the scope of rights as defined by patent claims. Effective patent protection requires a patent claim to be construed more broadly than its literal language.²² The doctrine of equivalents, created by judges to extend the coverage of a claim beyond its literal scope, allows a patent holder to exclude from the marketplace a competitive product that is either covered by the literal meaning of the claim or that presents an equivalent of the claimed invention.²³ The Supreme Court's opinion in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*,²⁴ however, has significantly restricted the reach of the doctrine through prosecution-history estoppel.²⁵ When the scope of a pharmaceutical patent claim is cut to its literal

companies appear to have gained more than they have lost—at the expense of pioneer companies.”).

19. The generic market share has increased from 49 percent in 2000 to 78 percent in 2010. PHARM. RESEARCH & MFRS. OF AM., *supra* note 10, at i. According to the Generic Pharmaceutical Association, 10,072 of the 12,751 listed drugs in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book,” have generic counterparts. *Facts at a Glance*, GENERIC PHARM. ASS'N, <http://www.gphaonline.org/about-gpha/about-generics/facts> (last visited Jan. 16, 2013). The Orange Book, available on the FDA's website, provides a list of patents related to drug products approved by the FDA. *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm> (last updated Nov. 16, 2012). Additionally, the generic industry is estimated to grow at an annual rate of more than 7.8 percent. *Facts at a Glance*, *supra*.

20. Henry G. Grabowski & Jeffrey L. Moe, *Impact of Economic, Regulatory and Patent Policies on Innovation in Cancer Chemoprevention*, 1 CANCER PREVENTION RES. 84, 86 (2008) (“For drugs with significant market sales at the time of patent expiration, the innovator's brand typically loses more than 90% of its market within a few months' time . . .”).

21. *See infra* Part I.B–C.

22. *See* Erin Conway, Note, *The Aftermath of Festo v. SMC: Is There “Some Other Reason” for Justifying the Third Festo Rebuttal Criterion?*, 82 CHI.-KENT L. REV. 1655, 1658 (2007) (“Because language is naturally ambiguous, and because a patentable invention is, by definition, something that does not already exist in the art, there are times when language cannot capture the essence of an invention.”).

23. *See infra* note 109 and accompanying text.

24. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002).

25. *See infra* notes 133–135 and accompanying text.

meaning, a generic manufacturer can make an insubstantial change to the patented invention and then outcompete the brand-name drug with the generic equivalent product. For example, a pharmaceutical formulation claimed purely by the structure of its components can be easily designed around by replacing one component with another that serves the same function but that has a slightly different structure.²⁶ Therefore, a patent without adequate scope cannot help the innovative firms recover their R&D investment, and this problem cannot be solved by a longer patent term.

In 1952, Congress enacted the new Patent Act (1952 Act),²⁷ which for the first time provided a statutory basis for MPF claims.²⁸ Unlike a purely structural claim, in which every element of an invention is defined by its structure, an MPF claim defines at least one element of the claimed invention by its function.²⁹ MPF claims can therefore be relatively difficult for generic manufacturers to design around, even with restricted application of the doctrine of equivalents. As in the example above, if one component of the claimed pharmaceutical formulation is defined by its function, a competitor cannot design around the claim by replacing it with a component that differs in structure but serves the same function.³⁰

Despite their statutory authorization, MPF claims remain largely unexplored in the pharmaceutical industry. Broader use of MPF claims would provide a more appropriate level of patent protection for pharmaceutical inventors, which in turn could translate into stronger economic incentives for investment. Because the application of MPF claims in other technology areas has encountered some conceptual and logical difficulties,³¹ this Note also examines related

26. MARTIN A. VOET, THE GENERIC CHALLENGE: UNDERSTANDING PATENTS, FDA AND PHARMACEUTICAL LIFE-CYCLE MANAGEMENT 29 (3d ed. 2011); *see also, e.g.*, Astra Aktiebolag v. Andrx Pharm., Inc., 222 F. Supp. 2d 423, 510–11 (S.D.N.Y. 2002) (holding that the generic microtablet did not infringe claim 11 of the of the Prilosec patent because the generic manufacturer designed around the claim by developing a formulation that did not require an alkaline reacting compound in its core).

27. Patent Act, ch. 950, 66 Stat. 792 (1952) (codified as amended at 35 U.S.C.).

28. *Id.* § 112, 66 Stat. at 798 (codified as amended at 35 U.S.C. § 112 (2006)), *amended by* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011); *see also infra* notes 165–167 and accompanying text.

29. *See infra* Part III.

30. *See infra* Part III.B.

31. For a general discussion of the issues encountered when MPF claims are applied in other technology areas, see Charles W. Bradley, *Means-Plus-Function Clauses in Patent Claims: A Tortuous Path*, 33 RUTGERS COMPUTER & TECH. L.J. 1 (2006); and John F. Triggs,

issues that can be expected to accompany the application of MPF clauses in pharmaceutical patents.

Part I analyzes the influence of the Hatch-Waxman Act, finding that despite its dual purposes—to stimulate innovation and spur generic development—it has primarily favored generic manufacturers and increased innovative firms' reliance on patent protection. Part II discusses the issue of adequate claim scope for pharmaceutical patents, focusing on the consequences of the restriction on the doctrine of equivalents. It finds that the current system does not properly protect innovative firms from challenges encouraged by the Hatch-Waxman Act. Part III argues that MPF claims should be used more frequently in pharmaceutical patents, which could provide innovative firms with a more appropriate level of protection than that which already exists.

I. THE HATCH-WAXMAN ACT AND THE RESULTING INCREASED NEED FOR ADEQUATE PATENT PROTECTION

In 1984, Congress enacted the Hatch-Waxman Act to achieve two conflicting, yet related, policy objectives: ensuring timely, affordable public access to drugs and encouraging new product development.³² Although intended to benefit both innovative firms and generic manufacturers, the Hatch-Waxman Act has mainly benefitted generic manufacturers by accelerating the market entry of generic drugs. Additionally, the Hatch-Waxman Act has resulted in heavily restricted trade-secret protection for innovative firms in the United States, leading these firms to depend almost exclusively on the patent system to profit. This Part briefly reviews the history and relevant provisions of the Hatch-Waxman Act and discusses how it has influenced pharmaceutical innovation.

A. *History and Background of the Hatch-Waxman Act*

1. *Prior Drug Regulation.* The Hatch-Waxman Act tried to solve problems following two earlier regulations of drugs—the Food, Drug, and Cosmetic Act of 1938 (FDCA)³³ and the 1962 Kefauver-Harris

Functional Claiming: § 112 ¶ 6 Still Difficult After All These Years, LANDSLIDE, Jan.–Feb. 2011, at 31.

32. Colleen Kelly, Note, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 417 (2011).

33. Federal Food, Drug, and Cosmetic Act, ch. 653, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–399d (2006 & Supp. V 2012)).

Amendment (1962 Amendment).³⁴ The FDCA was the first federal law to require testing to ensure drug safety.³⁵ Pursuant to the FDCA, pharmaceutical manufacturers must submit to the FDA a New Drug Application (NDA), which includes safety-testing results. The FDCA also imbued the FDA with the authority to prohibit the marketing of drugs that it deemed unsafe or that lacked sufficient safety data.³⁶ Later, Congress enacted the 1962 Amendment, which changed the NDA from a premarket notification process into an affirmative approval system.³⁷ Under the new system, drug manufacturers are required to submit data demonstrating both safety and efficacy for every new drug and are prohibited from using the new drug in the marketplace until obtaining affirmative approval from the FDA.³⁸

2. *Issues with Patent Terms.* Following the 1962 Amendment, patent-term adjustment became a highly debated issue. Innovative firms felt that the new law had shortened the effective patent term for new drugs, whereas generic manufacturers felt the patent terms were improperly extended.³⁹ Innovative manufacturers also raised concerns about the reduced incentives for R&D investment in new drug products because the heightened regulatory standard resulted in a lengthened approval process.⁴⁰ For innovative firms, which are usually forced to file patent applications immediately after the discovery of a potential drug candidate,⁴¹ the longer approval process meant shorter

34. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended in scattered sections of 21 U.S.C.).

35. Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER, Jan.-Feb. 2006, at 14, 17.

36. Patricia I. Carter, *Federal Regulation of Pharmaceuticals in the United States and Canada*, 21 LOY. L.A. INT'L & COMP. L.J. 215, 218-19 (1999).

37. Drug Amendments of 1962, § 104(a), 76 Stat. at 784 (codified as amended at 21 U.S.C. § 355(a)).

38. Kelly, *supra* note 32, at 420.

39. See Gidcumb, *supra* note 3, at 32-33 ("[P]atent holders felt that they lost effective patent term time and significant amounts of potential profit because of the delay in gaining FDA approval. . . [Generic manufactures found there to be] a 'de facto' extension to the patent term." (quoting Edward V. Filardi, *Patent Issues That Both Regulatory Affairs Personnel and Patent Attorneys Should Understand*, 54 FOOD & DRUG L.J. 215, 215 (1999))).

40. Between 1958 and 1979, the number of new FDA-approved products fell by 81 percent. Matthew Hinsch, *Hoecsht-Roussel Pharmaceuticals, Inc. v. Lehman*, 13 BERKELEY TECH. L.J. 163, 163-64 (1998). The decline was largely attributed to the heightened standard of the FDA-approval process. *Id.* at 164.

41. Inadvertent disclosure can make an otherwise-patentable invention fail the "novelty" requirement of patentability. 35 U.S.C. § 102 (2006), *amended by Leahy-Smith America Invents Act*, Pub. L. No. 112-29, § 3(b)(1), (n), 125 Stat. 284, 285, 293 (2011). This condition will still be

effective patent terms because the clock for a patent term might start running years before the patented drug product was approved for marketing.⁴² As a result, the heightened regulatory standard without a corresponding patent-term adjustment caused significant economic loss for innovative firms.⁴³

While innovative firms clamored for a restoration of the effective patent term lost during the regulatory review processes as a result of the 1962 Amendment, generic manufacturers also lobbied for a change in patent law to allow earlier market entry for their products. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,⁴⁴ the Federal Circuit held that a generic competitor's use of a patented ingredient to perform tests for the purpose of obtaining FDA approval of its product infringed the patent.⁴⁵ Accordingly, generic manufacturers could not begin to test their versions of brand-name drugs until related patents had expired, which, the generic manufacturers argued, amounted to a de facto extension to the patent term.⁴⁶

B. Relevant Provisions in the Hatch-Waxman Act

The Hatch-Waxman Act amended patent law to address patent-term adjustment. It also provided a new drug regulatory scheme that superseded all prior FDA policies and procedures governing the marketing and approval of generic drugs.⁴⁷ Among other things, the new scheme established a certification process for generic manufacturers to challenge drug patents, which has since resulted in

true under the Leahy-Smith America Invents Act (America Invents Act), Pub. L. No. 112-29, 125 Stat. 284 (2011), when its first-inventor-to-file provisions become effective on March 16, 2013, *id.* § 3(n)(1), 125 Stat. at 293.

42. For example, if a new drug was patented three years before it was approved for marketing, the innovative firm lost the three years during which it derived no economic benefit.

43. Susan E. Kopp, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is It a Healthy Long Term Solution?*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 945, 971 (1989) ("The three years [needed to obtain FDA approval after NDA submission], combined with the average of seven to ten years of research expended to produce the drug, is far too great an investment of time and resources to be economically feasible . . .").

44. *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858 (Fed. Cir. 1984), *superseded by* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (codified as amended at 35 U.S.C. § 271(e) (2006 & Supp. IV 2011)).

45. *Id.* at 863 ("We cannot . . . allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes.").

46. Gidcumb, *supra* note 3, at 33.

47. Kelly, *supra* note 32, at 420.

controversial litigation and developed into a major form of generic competition against innovative firms.⁴⁸

1. *Changes in Patent Law: Patent-Term Adjustment and the Testing Exception for Generic Manufacturers.* The Hatch-Waxman Act addressed concerns from both innovative firms and generic manufacturers with respect to effective patent terms. First, it includes a patent-term restoration provision to remedy the loss in effective terms for drug patents caused by the lengthy regulatory processes.⁴⁹ The statute provides that the term of an eligible drug patent “shall be extended by the time equal to the regulatory review period for the approved product which period occurs after the date the patent is issued.”⁵⁰ The restoration is subject to limitations.⁵¹

Second, the Hatch-Waxman Act overrules *Bolar*, permitting generic manufacturers to use patented brand-name drugs before patent expiration for activities “reasonably related” to the purpose of seeking FDA approval of their drugs.⁵² With this provision, generic manufacturers can start the regulatory-review process for their products before relevant patents expire, which greatly accelerates the market entry of generic drugs.

2. *The New Scheme of Generic-Drug Regulation.* The Hatch-Waxman Act also revised the FDCA to streamline the regulatory-approval process for generic drugs by extending the use of the

48. See *infra* Part I.B.3.

49. This provision was passed under Title II of the Hatch-Waxman Act and codified at 35 U.S.C. § 156 (2006), as amended by Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 37, 125 Stat. 284, 341 (2011).

50. 35 U.S.C. § 156(c).

51. First, the maximum patent-term extension cannot exceed five years; second, the total patent term plus any restoration extension cannot exceed fourteen years from the date of FDA approval; third, the period that can be restored will be reduced by any period during which the applicant did not act with due diligence. *Id.* § 156(c)(1), (c)(3), (g)(6)(a). Some scholars view the fourteen-year limit as inadequate because many nondrug patents get a seventeen-year useful term. See, e.g., Sherry M. Knowles, *Fixing the Legal Framework for Pharmaceutical Research*, 327 SCIENCE 1083, 1083 (2010) (“This creates the situation where a relatively unregulated, simple, inexpensive invention may receive 17 years or more of useful patent term, whereas more expensive and important pharmaceutical innovations get useful patent terms capped at 14 years . . .”).

52. 35 U.S.C. § 271(e)(1) (“It shall not be an act of infringement to make, use, offer to sell, or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law . . .”).

Abbreviated New Drug Application (ANDA).⁵³ As a result, generic manufacturers can have their products more quickly and inexpensively approved for marketing. Under the new regulation, ANDA filers only need to submit data to show that their products are “bioequivalent[s]” of the brand-name drugs to gain FDA approval.⁵⁴ This process costs much less than a full NDA, which requires independent research and separate clinical data to prove the safety and efficacy of the drug products.⁵⁵

The Hatch-Waxman Act further facilitates ANDA filing by putting a statutory limit on data exclusivity for brand-name drugs. Prior to the Hatch-Waxman Act, the safety and efficacy data of drugs were treated as trade secrets, which were not accessible to other drug manufacturers or the public at large.⁵⁶ Under the new regulatory scheme, the safety and efficacy data of brand-name drugs enjoy only a limited time of exclusivity.⁵⁷ After the exclusivity period ends, generic companies can use the data to seek regulatory approval for their products in ANDA filings.⁵⁸ The Hatch-Waxman Act provides that the term of data exclusivity is limited to five years for drug products containing a New Chemical Entity (NCE).⁵⁹ For non-NCE drug products,⁶⁰ data exclusivity is limited to three years.⁶¹ Moreover,

53. 21 U.S.C. § 355(j) (2006 & Supp. V 2012). Before 1984, generic manufacturers could only use an ANDA for pre-1962 brand-name drugs that the FDA had deemed safe and effective under its Drug Efficacy Study Implementation program. Kelly, *supra* note 32, at 420. The Hatch-Waxman Act expanded the ANDA process to all post-1962 brand-name drugs. *Id.* at 421.

54. 21 U.S.C. § 355(j)(2)(A)(iv) (2006). “Bioequivalent” is defined in § 355(j)(8)(B).

55. Kelly, *supra* note 32, at 423. Additionally, generic companies can also choose to file a paper NDA, also known as a section 505(b)(2) NDA under the FDCA. *Id.* at 423 & n.62; *see also* 21 U.S.C. § 355(b)(2) (specifying the requirements for “[a]n application submitted . . . for a drug for which the investigations described [earlier in the section] and relied upon by the applicant for approval of the application were not conducted by or for the applicant”). A paper NDA is similar to a full NDA except that in a paper NDA, generic manufacturers can use published scientific data to demonstrate the safety and efficacy of their drugs. *Id.* at 423 n.62.

56. Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. CHI. L. REV. 93, 97–98 (2004).

57. 21 U.S.C. § 355(j)(5)(F)(i)–(iv).

58. *Id.*

59. *Id.* § 355(j)(5)(F)(ii). A “[n]ew chemical entity” is a drug that contains no “active moiety” that has been approved in another NDA. New Drug Product Exclusivity, 21 C.F.R. § 314.108(a) (2012). An “active moiety” is “the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt . . . or other noncovalent derivative . . . , responsible for the physiological or pharmacological action of the drug substance.” *Id.*

60. These products include new formulations or salts, new indications, new dosage forms, new dosage strengths, new routes of administration, or new combinations of previously approved drugs.

although the FDA cannot issue an approval for an equivalent generic product before the data-exclusivity period on the branded product expires, a generic company can file an ANDA for its version of a non-NCE product during the three-year period, anticipating an immediate approval at the end of the exclusivity period.⁶²

3. *Paragraph IV Challenges: The Intersection of Patent Law and Drug Law.* The ANDA process includes a mechanism by which the branded companies and generic manufacturers can resolve any patent disputes. The Hatch-Waxman Act requires branded companies to provide the FDA with a list of patents related to their drug products⁶³ and requires the FDA to make the lists publicly available⁶⁴ in its *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book.”⁶⁵ As part of the ANDA process, generic manufacturers are required to file a certification for each Orange Book patent listed under the drug that they intend to offer as a generic, stating: (1) the patent information has not been filed with the FDA, (2) the patent has expired, (3) the generic will not enter the market prior to the date on which the patent expires, or (4) the patent is invalid, unenforceable, and/or not infringed on by the new drug for which the application is submitted.⁶⁶ The fourth assertion is referred to as a “Paragraph IV certification.”⁶⁷

The Hatch-Waxman Act treats the ANDA, filed together with a Paragraph IV certification, as a technical act of patent infringement—otherwise known as a PIV challenge.⁶⁸ Thus, the innovative firms and generic manufacturers can resolve their patent dispute before the generic drug reaches the market. The innovative firm is promptly notified after an ANDA is filed with a Paragraph IV certification

61. 21 U.S.C. § 355(j)(5)(F)(iii)–(iv).

62. *See id.* (setting the date by which the FDA may “make the approval of an application . . . effective”).

63. *See id.* § 355(b)(1)(G) (“The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug . . . or which claims a method of using such drug . . .”).

64. *Id.* § 355(j)(7).

65. *See Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, *supra* note 19.

66. 21 U.S.C. § 355(j)(2)(A)(i)–(vii).

67. *E.g.*, *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1334 (Fed. Cir. 2007); *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1346 (Fed. Cir. 2003).

68. 35 U.S.C. § 271(e)(2) (Supp. IV 2011).

against its product.⁶⁹ Upon receiving the notice, the innovative firm has forty-five days to file a patent-infringement action against the generic competitor, the ANDA applicant. This action keeps the FDA from approving the ANDA until either the generic company successfully defends the case in court or for thirty months.⁷⁰ If, however, the innovator decides not to initiate an infringement action, the FDA can immediately approve the ANDA.⁷¹ To encourage ANDA filing, the Hatch-Waxman Act grants 180 days of market exclusivity to the first filer that succeeds in the PIV challenge, meaning that no other generic manufacturer can enter the market during this time with a competing equivalent product.⁷²

C. Influence on the Pharmaceutical Industry

The Hatch-Waxman Act has substantially shaped the pharmaceutical industry. Most significantly, the Hatch-Waxman Act has greatly emboldened generic competition against innovative firms in the form of a growing number of PIV challenges.⁷³ Although the Hatch-Waxman Act was designed partly to restore patent terms for innovators corresponding to the time lost during regulatory review, it is debatable whether this benefit has actually materialized.⁷⁴ As a result, innovative firms live in a relatively hostile environment wherein available patent protection is constantly vulnerable to challenges—often at the earliest possible moment—and trade-secret protection previously accorded indefinitely to safety and efficacy data is limited to a maximum of five years.⁷⁵ This underprotection of intellectual property rights is at least partly responsible for the financial problems faced by branded firms and the stifled pharmaceutical innovation—reflected by the drying up of new-product pipelines in pharmaceutical companies.⁷⁶

69. 21 U.S.C. § 355(j)(2)(B) (2006).

70. *Id.* § 355(j)(5)(B)(iii).

71. *Id.*

72. *Id.* § 355(j)(5)(B)(iv).

73. See Hemphill & Sampat, *supra* note 4, at 614 (“[T]he prevalence of [PIV] challenges has risen dramatically over the past 25 years . . .”).

74. In February 1988, forty extensions were granted to drug patents with an average of 1.8 years. Miller, *supra* note 18, at 107. Yet the average period of review for these drugs averaged 8.2 years. *Id.*

75. See *supra* Part I.B.2; *infra* Part I.C.3.

76. See Higgins & Graham, *supra* note 4, at 370 (“[O]ne particular U.S. regulation—the Paragraph IV patent challenge—is increasingly stifling new drug innovation . . .”).

1. *The Burgeoning of PIV Challenges.* The sharp increase in PIV challenges began after a Federal Circuit case decided in 2000, *Eli Lilly & Co. v. Barr Laboratories, Inc.*⁷⁷ In *Eli Lilly*, the generic company Barr Laboratories won a PIV challenge by invalidating one claim in the patent on the drug fluoxetine, known commercially as Prozac.⁷⁸ After *Eli Lilly*, both the number of generic companies that are active in PIV filing and the number of products being challenged have rapidly increased.⁷⁹ The number of lawsuits filed involving PIV challenges has gone up from thirty-five in 2001 to 242 in 2011, a more than sixfold increase.⁸⁰ As of November 2012, 243 products are under PIV challenges, and many are attacked by multiple generic manufacturers.⁸¹

This proliferation of PIV challenges is a direct result of the Hatch-Waxman Act. In addition to the much cheaper ANDA procedure, the 180-day market-exclusivity period also serves as a strong economic incentive for generic manufacturers to file an ANDA.⁸² Without competition, the successful generic challenger can price their products at a level close to that of the innovator, reaping significant economic gain.

As estimated by the Federal Trade Commission (FTC), the average revenue generated by a successful PIV challenge is \$60 million, whereas the average cost of a challenge is about \$5 million.⁸³ A generic company, then, only needs to win one in every twelve challenges to make a profit. In reality, generic companies have done much better than that. As provided by the FTC study, from 1992 to 2000, 72 percent of PIV challenges filed led to litigation, and generic companies won 42 percent of the cases.⁸⁴ The great economic return

77. *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955 (Fed. Cir. 2000); see also Gregory Glass, *Pharmaceutical Patent Challenges—Time for Reassessment?*, 3 NATURE REV.: DRUG DISCOVERY 1057, 1057 (2004) (“In the period from 1984 to 2000, only a few generics companies were equipped and willing to withstand the expenses of product development and ensuing legal battles. Starting in 2000, after Barr Labs successfully challenged the Lilly blockbuster fluoxetine (Prozac), these generics companies started to incorporate Paragraph IV patent challenges as part of their core business strategies.”).

78. *Eli Lilly & Co.*, 251 F.3d at 958–59.

79. Glass, *supra* note 77, at 1058.

80. Data are available at a subscription-based website. THE PARAGRAPH FOUR REPORT, <http://www.paragraphfour.com> (last visited Jan. 16, 2013).

81. *Id.*

82. 21 U.S.C. § 355(j)(5)(B)(iv) (2006).

83. Higgins & Graham, *supra* note 4, at 370.

84. *Id.* More recent data can be found in THE PARAGRAPH FOUR REPORT, *supra* note 80. Of the 320 PIV cases decided in U.S. district courts in recent years, the innovative firms won

from PIV challenges has led to the popularity of “prospecting” among generic companies—a business strategy whereby generic companies file a wide range of PIV challenges in the hope of winning a small fraction of those challenges.⁸⁵ Because patent litigation can easily cost millions of dollars, meritless PIV challenges have resulted in increased transaction costs to the patent system, which is especially problematic for start-ups and small innovative companies that lack the resources for litigation.

2. *Early Patent Challenges.* In addition to providing financial rewards, the Hatch-Waxman Act has enabled generic companies to file PIV challenges at an early stage of the patent term after the relevant regulatory exclusivity has expired.⁸⁶ By overruling *Bolar*, the Hatch-Waxman Act allows a generic manufacturer to use a patented product to conduct bioequivalency studies for the ANDA process.⁸⁷ After gathering sufficient data, the generic manufacturer can decide to push for market entry before the patent expires by filing a PIV challenge, alleging that the patent is invalid, unenforceable, not infringed by its product, or a combination thereof.

Because the regulatory review process for an ANDA is short,⁸⁸ the generic manufacturer can potentially enter the market long before the full statutory term of the patent expires. Even if it loses the PIV challenge, it can still market its drug immediately after the patent expires, years earlier than what was possible before 1984.⁸⁹

3. *Loss of Trade-Secret Protection for Innovative Firms.* Moreover, the data-exclusivity provisions of the Hatch-Waxman Act have significantly reduced trade-secret protection for innovative

only 95 (29.7 percent), whereas generic companies won 68 (21.3 percent), and 157 cases (49.1 percent) went to settlement. *Id.* The data were last updated in November 2012 and include the outcomes from all cases pending as of November 1, 2003. *Id.*

85. Hemphill & Sampat, *supra* note 4, at 614–15.

86. See C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 327 (2012) (demonstrating “a sharp[] increase for early [PIV] challenges” between 2001 and 2010).

87. See *supra* note 52 and accompanying text.

88. A generic company meeting the statutory requirements can file an ANDA and receive a response from the FDA within 150 days. 21 U.S.C. § 355(q)(1)(F) (Supp. V 2012), *as amended* by Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 1135, 126 Stat. 993, 1135 (2012).

89. See Wilson, *supra* note 18, at 510 (“With the benefits of shortened FDA approval [under the Hatch-Waxman Act] . . . , a generic drug has the ability to be on the market almost immediately after a pioneer patent expires.”).

firms. Hatch-Waxman's mandatory data disclosure meant loss of trade secrets, a hitherto significant barrier that protected innovative firms from generic competition. Generic manufacturers previously might not have been able to sell a particular drug on the market because they lacked the resources to obtain the safety and efficacy data required to obtain regulatory approval. Under the Hatch-Waxman Act, however, generic manufacturers have access to the data generated by the innovative firms after the data-exclusivity period expires and thus must only generate bioequivalency data to gain regulatory approval. Due to diminished trade-secret protection, innovative firms have had to rely more heavily on the patent system to protect their economic interests.

4. *Reduced Patent Protection for Innovators.* The rapid increase of PIV challenges has led to reduced patent protection for innovators because they lose market exclusivity if the relevant patents are found to be invalid, unenforceable, or noninfringed by the generic product. In reality, innovative firms are not only under attack,⁹⁰ but they are losing a significant number of these battles.⁹¹ Due to the prevalence of PIV challenges, the average market life for brand-name drugs facing a first generic entry between 2001 and 2010 is only twelve years despite the nominal sixteen-year patent term.⁹² Studies have also shown that the average market-exclusivity period has decreased significantly since the mid-1990s.⁹³ This decrease could reduce

90. As of November 2012, 132 branded companies have products that are under active PIV challenge. THE PARAGRAPH FOUR REPORT, *supra* note 80.

91. See *supra* note 84 and accompanying text. Also note that the data shown here underestimate the actual loss suffered by innovative firms because the fraction of ANDA filings with PIV challenges that do not lead to litigation has not been taken into account. One contributing factor for innovative firms to decide not to litigate is that they have only forty-five days to file the lawsuit upon receiving the notice of ANDA filing. See 21 U.S.C. § 355(c)(3)(C) (2006) (stating that approval of an application with a PIV certification will be effective immediately unless the patent holder brings an infringement action within the forty-five-day time frame). The innovative firms may also give up if they conclude that they will likely lose in court anyway. But for the PIV challenges, litigation would be commenced much later in time, if it occurred at all.

92. Hemphill & Sampat, *supra* note 86, at 336.

93. See Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491, 497 (2007) (reporting that the effective market life for the ten drugs has decreased from 13.8 years between 1995–2001 to 11.2 years between 2002–2005). But see Hemphill & Sampat, *supra* note 86, at 336 (concluding that the average effective market life for drug products did not change much between the 1990s and 2000s). Even if the overall effective market life has not decreased, the

anticipated profitability for potential drug products, making them less attractive to investors. Indeed, some innovative firms would assert that pervasive patent challenges pose a more severe problem than patent expiration.⁹⁴

These observations compel one question: Why are innovative firms losing so many PIV challenges? Or put differently, why do pharmaceutical patents appear so weak when under attack? The patent holders lose in two ways: first, the patent is found invalid, unenforceable, or both; second, the claim is so narrow in scope that it does not cover the alleged infringing product.⁹⁵ As discussed in Part II, patent claims tend to be narrowly construed due to judicially restrictive application of the doctrine of equivalents. Consequently, the actual protection afforded by many patents is slim in scope, which at least partially explains the failure of innovative firms to cope with the increase of PIV challenges. Although the problem of inadequate patent scope is not a product of the Hatch-Waxman Act, it has become particularly prevalent as the Hatch-Waxman Act has left innovative firms increasingly reliant on the patent system.

In summary, after enactment of the Hatch-Waxman Act in 1984, the prospecting strategy gained popularity among generic companies and created serious problems for innovative firms. As discussed in detail in Part II, these problems are further exacerbated by the inadequate claim scope of pharmaceutical patents, as construed by courts. These two factors combined have substantially contributed to the decrease in R&D investments and the drying up of new product pipelines in the pharmaceutical industry.

II. EFFECTIVE PATENT-CLAIM SCOPE: *FESTO* AND THE DOCTRINE OF EQUIVALENTS

To protect themselves from fierce generic competition, innovators rely heavily on the patent system. Restrictive application of the doctrine of equivalents, however, has unduly narrowed the claim scope of pharmaceutical patents and has significantly limited the patent protection available for innovators. Patents can only

patent term is less secure, the risk to the firm is higher, and the cost of drug development is increased due to litigation costs, all of which contribute to the loss of incentives for investors.

94. Glass, *supra* note 77, at 1057.

95. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2006) (providing that a successful PIV challenge requires a generic manufacturer to establish that “such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted”).

incentivize investment when they have the scope necessary to effectively confer the benefit of market exclusivity and thus help the innovators recoup their investments. If a patent claim has too narrow of a scope, competitors can use information disclosed in the patent to design around the slim-cut claim and develop an equivalent, yet noninfringing, product. Because a patent with a narrow scope may be worse than no patent at all in attracting investors,⁹⁶ granting adequate scope for patent claims is critical for the patent system to efficiently encourage R&D investment.

As Judge Raymond Clevenger of the Federal Circuit has noted, “[T]he name of the game is the claim.”⁹⁷ Claims are the most critical component of a patent because they mark the boundaries of an invention.⁹⁸ During prosecution,⁹⁹ claims are intensely scrutinized by examiners in the United States Patent and Trademark Office (USPTO) to determine their patentability.¹⁰⁰ During litigation, claim construction is performed as a preliminary matter in a separate hearing (also known as a *Markman* hearing)¹⁰¹ and often can be dispositive in determining the outcome of the case.¹⁰² For a long time in the U.S. patent system’s history, the doctrine of equivalents played

96. See Jean Burke Fordis & William L. Leschensky, *Advanced Bio/Chemical Claim Drafting Issues*, in ADVANCED PATENT PROSECUTION WORKSHOP 2009: CLAIM DRAFTING & AMENDMENT WRITING at 691, 738 (PLI Intellectual Prop., Course Handbook Series No. G-977, 2009) (“Claims that are drawn too narrowly give the invention away without adequate protection, and may be worse than no patent at all, which at least offers the possibility of trade secret protection and does not broadcast the invention to the world.”).

97. *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998).

98. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004))).

99. Prosecution of a patent describes the process whereby applicants or their representatives interact with an examiner at the United States Patent and Trademark Office (USPTO) with regard to a pending application for a patent.

100. See *Phillips*, 415 F.3d at 1316 (“[T]he rules of the PTO require that application claims must ‘conform to the invention . . . and the terms and phrases used in the claims must find clear support or antecedent basis’” (quoting 37 C.F.R. § 1.75(d)(1))).

101. See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 384 (1996) (“The [construction of patent claims] is a question of law, to be determined by the court” (quoting *Winans v. Denmead*, 56 U.S. (15 How.) 330, 338 (1854)) (internal quotation marks omitted)).

102. John M. Benassi, Melinda Luthin & David W. Mulliken, *Claim Construction and Proving Infringement: Impact of Phillips and Festo and Their Progeny*, in PATENT LITIGATION 2007, at 57, 65 (PLI Intellectual Prop., Course Handbook Series G-910, 2007) (“[A] claim term’s construction is often dispositive in determining claim validity in light of prior art.”).

a vital role in providing patents with adequate scope.¹⁰³ This doctrine, however, has been applied less consistently, even sparingly, in recent decades. This Part reviews the history of this doctrine and discusses how its restrictive application has affected pharmaceutical innovation, especially in view of the growing number of PIV challenges.

A. *The Doctrine of Equivalents*

Since the 1850s, the Supreme Court has used the doctrine of equivalents to provide adequate claim scope for patent holders.¹⁰⁴ To prove infringement, a patent holder must demonstrate that the claimed invention covers the alleged product, which requires construction of the terms in the claim.¹⁰⁵ Generally, courts interpret patent terms according to the “ordinary and customary meaning” of the words used.¹⁰⁶ But, due to the inherent ambiguity in and limitations of language, a literal reading of the patent claims sometimes cannot capture the essential scope of the invention.¹⁰⁷ Restricting the protection to the literal scope of claims could allow a competitor to make insubstantial modifications and avoid infringement.¹⁰⁸

The doctrine of equivalents broadens the claim’s scope beyond its literal boundaries. Under this doctrine, “a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.”¹⁰⁹ In other words, in situations in which patent holders cannot prove literal infringement because the

103. See Conway, *supra* note 22, at 1659 (“[T]he Supreme Court in *Winans v. Denmead*[], 56 U.S. (15 How.) 330 (1854),] adopted the doctrine of equivalents in 1853 . . .”).

104. *Id.*

105. See *Markman*, 517 U.S. at 374 (“Victory in an infringement suit requires a finding that the patent claim ‘covers the alleged infringer’s product or process,’ which in turn necessitates a determination of ‘what the words in the claim mean.’” (quoting HERBERT F. SCHWARTZ, PATENT LAW AND PRACTICE 80 (2d ed. 1995))).

106. See *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (“We have frequently stated that the words of a claim ‘are generally given their ordinary and customary meaning.’” (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996))).

107. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002).

108. See *id.* (“If patents were always interpreted by their literal terms, their value would be greatly diminished. Unimportant and insubstantial substitutes for certain elements could defeat the patent, and its value to inventors could be destroyed by simple acts of copying.”).

109. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)).

literal language of the claim does not cover the accused product, they can still prove infringement under the doctrine of equivalents by showing that the accused product is an equivalent of the claimed invention. To determine whether the alleged infringing product or process is an equivalent of the claimed invention, courts have developed a “function-way-result” test, which provides that equivalency will be found when “two devices do the same work in substantially the same way, and accomplish substantially the same result.”¹¹⁰

B. Prosecution-History Estoppel Under Festo

Application of the doctrine of equivalents is subject to a number of limitations, the most significant of which is prosecution-history estoppel.¹¹¹ Prosecution-history estoppel prevents patent holders from using the doctrine of equivalents to prove infringement if they have surrendered the subject matter at issue during prosecution proceedings.¹¹² In other words, if the subject matter is excluded from a claim by a narrowing amendment to comply with a patentability requirement, patent holders cannot reclaim it under the doctrine of equivalents during litigation. Thus, estoppel often provides a powerful check on the application of the doctrine of equivalents in the pharmaceutical industry, especially after the *Festo* decision.

In *Festo*, the Supreme Court reexamined the interaction between prosecution-history estoppel and the doctrine of equivalents and provided new guidelines for their application.¹¹³ Whether intended by the Court or not, the decision created a powerful estoppel that has resulted in a much more limited version of the doctrine of

110. *Mach. Co. v. Murphy*, 97 U.S. 120, 125 (1878). Courts have also examined the issue of equivalency by asking (1) whether there are only “insubstantial differences” between the accused device and claimed invention, *Dawn Equip. Co. v. Ky. Farms Inc.*, 140 F.3d 1009, 1015 (Fed. Cir. 1998) (internal quotation marks omitted); or (2) whether the claimed limitation is interchangeable with the corresponding elements in the accused device, *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1535 (Fed. Cir. 1987).

111. *Benassi et al.*, *supra* note 102, at 93–94. Other limitations on the doctrine of equivalents include the all-element rule, the public-dedication rule, and prior art. *Id.* at 93. Briefly, the all-element rule states that the doctrine applies to each discrete element of the claim rather than to the whole invention. *Id.* at 94. The public-dedication rule provides that the doctrine cannot be used to recapture unclaimed subject matter that has already been disclosed to the public in the patent application. *Id.* Finally, the scope of a patent cannot be extended to cover prior art. *Id.*

112. *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1376 (Fed. Cir. 1999).

113. *Festo*, 535 U.S. at 736, 740.

equivalents.¹¹⁴ In short, the Court revisited the policy justifications for both doctrines and relied on its precedents to hold the following: First, a narrowing amendment¹¹⁵ made to satisfy *any* patentability requirement may give rise to estoppel.¹¹⁶ Second, estoppel establishes a presumption of a complete bar for invoking the doctrine of equivalents unless the patent holder carries the burden to show that the amendment does not surrender the particular equivalent in question.¹¹⁷

The first holding greatly expands the reach of prosecution-history estoppel. Before a patent can be issued, it must satisfy a set of statutory requirements both with respect to its substance and to its formality. The claimed subject matter must be useful, novel, and nonobvious,¹¹⁸ and the patent application must describe and enable the embodiment of the invention.¹¹⁹ In prior cases, prosecution-history estoppel had only been applied “where claims have been amended for a limited set of reasons [related to subject matter], such as to avoid prior art, or otherwise to address a specific concern—such as obviousness.”¹²⁰ In *Festo*, the Court explicitly rejected this substance-based categorical limitation on the application of estoppel, reasoning that any amendment, if not “truly cosmetic,” would narrow the patent-claim scope and raise the estoppel issue.¹²¹

Regarding the effect of establishing estoppel, the Court framed the question as, “Does the estoppel bar the inventor from asserting infringement against *any* equivalent to the narrowed element or

114. See *infra* notes 133–135 and accompanying text.

115. An amendment is the procedure by which the patent applicant, while prosecuting a patent from the USPTO, makes changes to the initially submitted patent claims to satisfy patentability requirements. The amendments can be either substantive or formalistic and can either broaden or narrow the scope of the claim.

116. *Festo*, 535 U.S. at 736.

117. *Id.* at 740.

118. 35 U.S.C. §§ 101–103 (2006), as amended by Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(b)(1), (c), (n), 125 Stat. 284, 285, 287, 293 (2011).

119. *Id.* § 112(a) (2006), as amended by Leahy-Smith America Invents Act, § 4(c), 125 Stat. at 296.

120. *Festo*, 535 U.S. at 735 (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 30–32 (1997)).

121. *Id.* at 736–37. According to the Court, a patent holder who has amended “a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art [to satisfy the subject matter requirement,] or to comply with § 112 [to satisfy the formality requirement].” *Id.* at 737.

might some equivalents still infringe?”¹²² With the holding of the “presumption” rule, estoppel establishes a presumption of a complete bar for asserting equivalents. This presumption is only rebuttable when the patent holder proves that

[t]he equivalent may have been *unforeseeable* at the time of the application; the rationale underlying the amendment may bear *no more than a tangential relation* to the equivalent in question; or there may be *some other reason* suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question.¹²³

In reaching these holdings, the Supreme Court emphasized the “notice” goal of patent law.¹²⁴ Patent law requires that inventors describe their inventions in “full, clear, concise, and exact terms” to receive the benefit of patent protection.¹²⁵ This requirement seeks to make boundaries of patent claims as clear as possible to promote efficient investment in innovation.¹²⁶ Without knowing with some certainty where a patent’s exclusionary rights end, competitors might be deterred from manufacturing legitimate products that are outside of the scope of the patent.¹²⁷ They might also accidentally invest in products that are secured by a patent, resulting in inefficient allocation of resources and wasteful litigation.¹²⁸

The doctrine of equivalents, while serving the critical role of ensuring fair value for patents, simultaneously makes the scope of patents uncertain because of the difficulty in anticipating the entire breadth of equivalents. To alleviate this uncertainty, prosecution-history estoppel provides that the prosecution proceedings in the USPTO should be examined to determine the proper scope of

122. *Id.* at 740–41 (emphasis added). The Court of Appeals adopted a “complete bar” rule, which would disallow any assertion of equivalent and reduce the claim scope to its “strict literal terms.” *Id.* at 737. The Supreme Court deemed this per se rule to be unprecedented, *id.*, and found that it might have jeopardized the “balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision,” *id.* at 739.

123. *Id.* at 740–41 (emphasis added).

124. *Id.* at 739.

125. 35 U.S.C. § 112 (2006), *as amended by* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011). This particular requirement does not change after the America Invents Act.

126. *Festo*, 535 U.S. at 730–31.

127. *Id.* at 732.

128. *Id.*

equivalents for any element of a claim.¹²⁹ An applicant who has narrowed a claim element to overcome a rejection during prosecution is thus prohibited from arguing in subsequent litigation that the surrendered subject matter should be deemed as equivalent to the literal claims of the issued patents.¹³⁰ Therefore, prosecution-history estoppel provides checks on the reach of the doctrine of equivalents and ensures that its application “remains tied to its underlying purpose.”¹³¹

Festo first appeared to be a victory for patent holders because they were granted the opportunity to rebut the presumption of a complete bar to the doctrine of equivalents when estoppel is in effect.¹³² Due to the practical difficulty in rebutting the presumption¹³³ and the strict rule that any narrowing amendment, substantive or not, creates a presumption of estoppel, *Festo* actually resulted in an estoppel doctrine so powerful that it has practically eliminated the doctrine of equivalents.¹³⁴ In fact, in light of this ruling and subsequent cases, some practitioners have suggested that “it appears likely that only those patents that make it through the PTO unamended will enjoy the previous scope of the doctrine of equivalents.”¹³⁵

C. Effects of *Festo* on PIV Challenges: A Hypothetical

As discussed in Part I, the increasing use of PIV challenges by generic manufacturers following the enactment of the Hatch-Waxman Act has become a major threat to innovative pharmaceutical companies, as they face constant challenges to their patents and actually lose many of those battles. One important factor that contributes to their losses is the restrictive application of the doctrine of equivalents under *Festo*, which makes it much easier for the generic manufacturers to design around the patent.

There are three major types of pharmaceutical patents: drug-substance patents, which claim the active ingredients of drugs (also known as AI patents); drug-product patents, which claim either

129. *Id.* at 733.

130. *Id.* at 733–34.

131. *Id.* at 734–35.

132. See *supra* note 123 and accompanying text.

133. See Benassi et al., *supra* note 102, at 66 (“[F]or patentees, this rebuttal opportunity turned out to be more hype than hope . . . because of practical obstacles to producing compelling evidence that will suffice to rebut the presumption.”).

134. Triggs, *supra* note 31, at 31.

135. Benassi et al., *supra* note 102, at 67.

particular drug formulations or compositions; and finally, method-of-use patents, which claim various therapeutic indications of a specific drug.¹³⁶ This Section uses a drug-product patent claim as an example to illustrate how the restricted application of the doctrine of equivalents under *Festo* fails to provide appropriate protection for innovators.

Assume that an innovative firm (Innovator) has spent millions of dollars to develop a new formulation of its drug X. The patent of the formulation is listed as drug X in the Orange Book, and a generic manufacturer (Generic) files a PIV challenge alleging that its own version of drug X, X1, does not infringe Innovator's patent. A drug formulation often contains active ingredients plus an inert carrier, which usually helps optimize the effect of the drug through a variety of mechanisms.¹³⁷ Here, assume that X comprises three elements: two active ingredients, A and B, plus a specific carrier C, which improves A's absorption by the human body. The active ingredients A and B are critical to the drug's efficacy and safety and cannot be easily replaced.¹³⁸ There may be a number of potential substituents for carrier C that, much like carrier C, improve A's absorption through the same mechanism. These substituents usually can be easily identified according to the specific mechanism of C as revealed in the patent. Here, assume that Generic has identified carrier C1 as a replacement of C and developed X1 that comprises A, B, and C1. All Generic needs to do to gain FDA approval for X1 is to demonstrate that X1 is a bioequivalent to X, which should be relatively easy.

When Generic files the ANDA for drug X1, Innovator will receive a notice and have forty-five days to file a lawsuit to allege infringement. If Innovator fails to do so, X1 will be considered noninfringing and can enter the market as soon as the regulatory exclusivity period for X ends and the ANDA is approved. Because X is a new formula, which is a non-NCE drug product,¹³⁹ it only enjoys three years of data exclusivity and the ANDA for X1 can be

136. Submission of Patent Information, 21 C.F.R. § 314.53 (2012).

137. See *U.S. FDA Drug Definitions*, REGISTRAR CORP, <http://www.registrarcorp.com/fda-guidance/fda-definitions/drugs.jsp> (last visited Jan. 16, 2012) (defining pharmaceutical formulation as "the process in which different chemical substances, including the active drug, are combined to produce a final medicinal product").

138. See 21 U.S.C. § 355(j)(2)(A)(ii) (2006) (providing that generic manufacturers will not be able to get ANDA approval if they change the active ingredients), *as amended* by Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, 126 Stat. 993 (2012).

139. See *supra* notes 59–60 and accompanying text.

approved immediately after the three-year period expires.¹⁴⁰ If Innovator, however, chooses to litigate and succeeds in the litigation, it will enjoy the full twenty-year term of patent protection,¹⁴¹ several times longer than the data-exclusivity period. Thus, the difference in potential economic return for Innovator between the two scenarios is quite substantial.

Assuming that Innovator has timely initiated the lawsuit, what would be the likely outcome? Because drug X1 does not use C as its carrier, the literal scope of the patent does not cover X1, and Innovator's only hope is to win under the doctrine of equivalents. Under *Festo*, the threshold issue is whether the carrier claim element has been narrowed to satisfy the patentability requirement.¹⁴² Assuming, as is often the case, that the element was amended to C from a broader recitation encompassing C,¹⁴³ the *Festo* ruling applies and the carrier element is limited to its literal scope—C but not C's equivalents. Consequently, unless Innovator establishes one of the three exceptions to the *Festo* presumption, which is difficult to do,¹⁴⁴ estoppel will apply and Generic will likely win on noninfringement, causing Innovator to lose most of its market for X a few months after the three-year exclusivity period ends.¹⁴⁵

The scenario described above is not unusual in today's pharmaceutical industry, and it can at least partially explain why innovative firms are losing so many patent battles.¹⁴⁶ One might argue, however, that this example only represents non-AI patents, which are by nature less novel or innovative than AI patents. As a matter of fact, an empirical study published in 2011 found that generic

140. See *supra* notes 60–62 and accompanying text.

141. See 35 U.S.C. § 154(a)(2) (2006) (providing for twenty-year terms), as amended by Leahy-Smith America Invents Act, Pub. L. No. 112-29, §§ 3(j), 20(j)(1), 125 Stat. 284, 290, 335 (2011).

142. See *supra* note 130 and accompanying text.

143. This is especially likely to happen if the patent was issued before the *Festo* ruling because *Festo* strongly discourages narrowing amendments. See *supra* notes 134–135 and accompanying text.

144. See *supra* note 133 and accompanying text.

145. See Grabowski & Kyle, *supra* note 93, at 492 (2007) (observing that generics enter the market “usually within a few months of patent expiration”). This is particularly true because *Festo*'s applicability may be so straightforward that Innovator declines to bring Hatch-Waxman litigation against Generic.

146. For a discussion of the Hatch-Waxman Act's influence on the pharmaceutical industry, see *supra* Part I.C.

manufacturers preferentially attack non-AI patents,¹⁴⁷ particularly formulation patents.¹⁴⁸ Additionally, because it is often alleged that innovative firms increasingly adopt the so-called “evergreening” strategy in which they obtain additional non-AI patents on related products with the same active ingredients to extend market exclusivity after the AI patent expires, some scholars argue that PIV challenges, through specifically targeting and practically eliminating those “non-meritorious” patents, provide a mechanism to balance this “evergreening” strategy.¹⁴⁹

One possible implication of these observations is that the failure of innovative firms to cope with pervasive PIV challenges may not be a sign of the patent system’s failure to provide adequate protection. Rather, it may indicate that the system is working properly to exclude “non-meritorious” patents.¹⁵⁰ Granted, the limitation of the doctrine of equivalents does not affect AI patents as much as it affects non-AI patents, as designing around an active ingredient can be extremely difficult.

This viewpoint, however, is problematic, mainly because non-AI patents, although narrower in scope, do not inherently merit less protection than AI patents. First, products protected by non-AI patents, such as improved formulations or new indications, still require substantial R&D investment.¹⁵¹ A reasonable prospect of patent-protected market exclusivity for these products is also necessary to incentivize investment in their development. Second, a start-up drug company sometimes must rely exclusively on non-AI patents because the core active ingredients are unpatentable due to inadvertent premature disclosure.¹⁵² Although non-AI patents might

147. See Hemphill & Sampat, *supra* note 4, at 643 (“Non-AI patents have a strong positive relationship with challenges, especially those generating extra nominal patent term.”).

148. See *id.* at 621 (“In comparison to AI patents, patents for particular formulations—for example, a chemical mechanism providing sustained release of the drug substance over time—are more open to attack.”).

149. Hemphill & Sampat, *supra* note 86, at 337 (“[PIV] challenges may reflect society’s strongest defense against non-meritorious patents that would harm payers and patients.”).

150. *Id.*

151. See Grabowski & Moe, *supra* note 20, at 85 (“Even after a product is approved for marketing, extensive R&D expenditures are frequently undertaken for new indications and improved formulations. Studies to establish new indications typically involve expenditures of well over \$100 million but can be substantially greater . . .”).

152. See Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 517 (2009) (“[I]t is not uncommon for new drugs to be disclosed prematurely such that they cannot be patented later.”).

yield some hope for the developers of these products, this hope is much diminished because non-AI patents are vulnerable targets of PIV challenges.¹⁵³ Indeed, pharmaceutical companies are known to screen out potential drug candidates for which they cannot get an AI patent due to unintended disclosure.¹⁵⁴

Finally, as also noted in the 2011 study,¹⁵⁵ these so-called “weak” non-AI patents provide incremental benefit to the brand-name firms, and it is questionable “whether, absent the incremental protection provided by these weak patents, brand-name firms would have sufficient incentives to invest in socially valuable research.”¹⁵⁶ Indeed, many important drug products rely on formulation patents or method-of-use patents.¹⁵⁷ Therefore, the “just merit” of a patent—that is, the amount of protection the patent deserves—is more appropriately decided by a case-by-case analysis rather than by labeling it as either an AI patent or a non-AI patent. Non-AI patents also deserve adequate protection, which the current system does not afford due to the undue restriction on the doctrine of equivalents.

In summary, the recent decline in pharmaceutical innovation suggests that the patent system provides inadequate financial incentives for innovation. At a minimum, the sharp increase in PIV challenges and the restrictive application of the doctrine of equivalents have contributed to this inadequacy. In general, patent protection has two independent dimensions: the time (effective patent life) and the scope (coverage of patent claims). In recent years, the effective life for drug patents has become partially dependent on adequate patent scope because of the popularity of PIV challenges. When innovative firms lose a PIV challenge for noninfringement, the effective life for that patent term is over with respect to at least that generic challenger, even if the validity and enforceability of that patent is still upheld.

153. See *supra* notes 147–148 and accompanying text.

154. See Roin, *supra* note 152, at 507 (“[I]t is not unusual for a pharmaceutical company to sour on an otherwise promising drug candidate after their attorneys turn up a prior disclosure that threatens its patent protection.”).

155. See *supra* note 147 and accompanying text.

156. Hemphill & Sampat, *supra* note 4, at 643.

157. See Grabowski & Moe, *supra* note 20, at 87 (“It is worth noting that many important drug products, such as the first AIDS therapy, AZT (zidovudine), relied on formulation or methods of use patents because their product patents had already expired. This could also be the case for many chemoprevention agents.”).

There are at least three possible solutions to this problem. To spur pharmaceutical innovation, the industry needs (1) a more effective parallel system to provide nonpatent protection for inventors, such as a significantly longer data-exclusivity period for brand-name drugs, (2) a less restrictive application of the doctrine of equivalents with an attendant broader scope for pharmaceutical patents, or (3) a wider application of MPF claims.¹⁵⁸ The first approach requires major legislative efforts to modify current drug law, and the second approach requires a reversal of Supreme Court jurisprudence on the issue of the doctrine of equivalents. In comparison, the third approach—the application of MPF claims—is simply an exercise of statutorily granted claiming strategy, can be easily implemented, and may prove to be an efficient solution in certain contexts.

III. APPLICATION OF CLAIMS WITH MEANS-PLUS-FUNCTION CLAUSES IN PHARMACEUTICAL PATENTS

Means-plus-function clauses for patent claims were codified in the 1952 Act, 35 U.S.C. § 112, ¶ 6 (now § 112(f)), which provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.¹⁵⁹

This provision consists of two parts. The first expressly authorizes a patent applicant to claim an element of a combination by its function, rather than by its structure.¹⁶⁰ The second provides guidance on construction of claims including such elements.¹⁶¹ As prescribed in the statute, the literal scope of an MPF claim covers the “corresponding structure . . . and equivalents thereof.”¹⁶²

158. MPF claims, although authorized in the 1952 Act, have not been explored much in pharmaceutical patents.

159. 35 U.S.C. § 112 (2006), *amended by* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011). Note that the America Invents Act does not change this provision substantively.

160. *See id.* (“An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof . . .”).

161. *See id.* (“[S]uch claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.”).

162. *Id.*

Consequently, with the doctrine of equivalents not in play, the literal scope of a purely structural claim does not cover a product that contains a slight variation to the claimed structure, whereas that of an MPF claim does, as long as the product serves the same function and contains an equivalent structure as the claimed invention.¹⁶³ Therefore, the special nature of an MPF clause makes this claim strategy a promising solution to rectify the problem of inadequate claim scope by providing a broader literal claim scope.

Although authorized by Congress sixty years ago, MPF claims have barely been explored in the pharmaceutical industry. The special nature of MPF claims, however, has generated certain interpretative or logical difficulties when applied in other technology fields.¹⁶⁴ This Part briefly reviews the legal foundation of MPF claims, analyzes their potential in promoting pharmaceutical innovation, and discusses issues that might arise during their application.

A. *The Rationale Behind MPF Claims*

To provide more flexibility in claim drafting, Congress included § 112 ¶ 6 in the 1952 Act to specifically authorize applications for MPF claims.¹⁶⁵ Patent law has never strictly required nonfunctional language for patent claims.¹⁶⁶ Functional language can offer advantages over pure structural description in certain contexts and has been accepted by courts long before the codification of MPF claims.¹⁶⁷

163. See *infra* note 188 and accompanying text.

164. See *supra* note 31.

165. See Bradley, *supra* note 31, at 2 (“In response to the [*Halliburton Oil Well Cementing Co. v. Walker*, 329 U.S. 1 (1946),] decision, Congress enacted the . . . provision, now codified as § 112, paragraph 6 to authorize the use of means-plus-function clauses”); Rudolph P. Hofmann, Jr. & Edward P. Heller, III, *The Rosetta Stone for the Doctrines of Means-Plus-Function Patent Claims*, 23 RUTGERS COMPUTER & TECH. L.J. 227, 243 (1997) (“By far the most accepted reason [for the enactment of § 112(f)] is that the drafters intended to overrule the Supreme Court’s decision in *Halliburton Oil Well Cementing Co. v. Walker*.”).

166. Hofmann & Heller, *supra* note 165, at 245. Prior to the 1952 Act, the Supreme Court briefly invalidated patents written in means-plus-function format and forbade claims that “use ‘conveniently functional language at the exact point of novelty.’” *Halliburton*, 329 U.S. at 8–9 (quoting *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 371 (1938)). The Supreme Court’s objection was not to functional claim language in general, but to its particular application at the “point of novelty.” *Id.* at 8. Nonetheless, the 1952 Act specifically overrode *Halliburton*. See Patent Act, ch. 950, § 112, 66 Stat. 792, 798 (1952) (codified as amended at 35 U.S.C. § 112 (2006)) (allowing for MPF claims), amended by Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011).

167. In the case of *Corning v. Burden*, 56 U.S. (15 How.) 252 (1854), the Supreme Court examined a patent claim written with functional language and held that the claim should be

Both the statutory language and the legislative history of the 1952 Act clearly indicate that § 112 ¶ 6 was enacted to provide a drafting option to patent prosecutors. Pasquale J. Federico, an Examiner-in-Chief at the USPTO who wrote the first draft of the 1952 Act, stated that “[i]t is unquestionable that some measure of greater liberality in the use of functional expressions in combination claims is authorized.”¹⁶⁸ Contrary to the drafter’s intention, however, the application of the second half of § 112 ¶ 6 has become more commonly sought by alleged infringers as a way to narrow claim scope and avoid liability in litigation since the 1990s.¹⁶⁹

B. The Potential for MPF Claims in Pharmaceutical Patents

MPF claims hold great potential for pharmaceutical patents for several reasons. First, based on the nature of pharmaceutical patents, application of MPF claims was actually contemplated by the drafters of the 1952 Act. Second, an MPF claim can be more commensurate in scope with a disclosed invention than a pure structural claim, offering clarity and better notice to the public. Finally, wider application of MPF claims in pharmaceutical patents can provide a solution to the problem of inadequate patent scope as highlighted in Part II, which may in turn enable the patent system to more efficiently promote pharmaceutical innovation.

First, the application of MPF claims in pharmaceutical patents fits the intentions of the drafters of the 1952 Act because both drug-product claims and method-of-use claims can include at least one functional element. In describing the application of § 112 ¶ 6, Federico emphasized that one or more functional elements can be applied in a claim for a combination, which “may be not only a combination of mechanical elements, but also a combination of

construed to cover the machine disclosed in the specification that performed the function, *see id.* at 269 (“The patent of Burden alleges no discovery of a new process, but only that he has invented a machine, and, therefore, correctly states the nature of his invention.”). The fact that the Court did not reject the validity of the patent claim indicated that it permitted the use of functional language. In *Continental Paper Bag Co. v. Eastern Paper Bag Co.*, 210 U.S. 405 (1908), the Supreme Court again held that the claimed “operating means” for a particular functional purpose covered both the corresponding machine in the specification that achieved the stated purpose and the machine’s equivalents, *id.* at 417, 422.

168. P.J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC’Y 161, 186 (1993).

169. *See* Triggs, *supra* note 31, at 31 (“[O]ver the last 15 years, the way courts have identified and treated such § 112 ¶ 6 functional claims has evolved as a way to limit the patent rights.”).

substances in a *composition claim*, or steps in a process claim.”¹⁷⁰ As described in Part II.C, most pharmaceutical patents fall into one of three major categories: drug-substance patents, drug-product (formulation and composition) patents, and method-of-use (therapeutic indications) patents.¹⁷¹ Both drug-product claims and method-of-use claims are the most likely claims for combinations that can include one or more functional elements, especially formulation drug-product claims.

Second, functional language can add accuracy and clarity to a patent in certain situations, providing the public with clear notice of the boundaries of the claim. Patent claims are statutorily required to be supported by a written description and be commensurate in scope with the enabling disclosure.¹⁷² Importantly, the language should be sufficiently clear to provide notice to the public regarding what has been claimed and what can still be freely explored.¹⁷³ As the legislative history of the 1952 Act suggests, the special authorization of MPF claims was also partly motivated by the ability of those claims to describe an invention more precisely than structural claims.¹⁷⁴

Again consider the formulation claim of drug X that comprises three elements: active ingredients A and B, plus a carrier C that improves the absorption of A. Assume that the essence of the invention is the discovery that the inefficient absorption of A significantly reduces the efficacy of the drug, and that carrier C cures this defect through a novel mechanism. A claim element stating “a means for improving absorption of A” that is construed by linking the improved absorption to carrier C in the specification would more accurately capture the essence of the invention than would an element merely describing the structure of C. Moreover, the

170. Federico, *supra* note 168, at 186 (emphasis added).

171. See *supra* text accompanying note 136.

172. 35 U.S.C. § 112 (2006), amended by Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011).

173. See *id.* (“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or joint inventor regards as the invention.”).

174. See *Patent Law Codification and Revision: Hearing on H.R. 3760 Before H. Subcomm. No. 3 of the Comm. on the Judiciary*, 82d Cong. 71 (1951) (statement of Cecil C. Kent, Esq., Fetherstonhaugh & Kent) (“[F]unctional form of claim . . . is the most perfect way to define a given structure with deductive inevitability. And it has the advantage of clearness of meaning. This greater clearness of meaning arises from the fact that a common, already existing word . . . cannot bring a definite understanding about unknown structure, and every invention involves some unknown or new structure naturally.”).

functional language clarifies to potential competitors that the patent covers a drug comprising A, B, and a carrier that is the structural equivalent to C that improves A's absorption just as C does. Therefore, the functional language enables the claim to more precisely define the invention, providing the public with clear notice of the literal boundaries of what has been claimed.

Finally, MPF claims provide a potential cure for the problem of inadequate scope for pharmaceutical patents. In the previous hypothetical, with the information provided in Innovator's patent, Generic developed drug X1—the generic version of X—with the substitution of carrier C with C1, which is a structural equivalent to C and improves A's absorption in the same manner as C. If the patent is limited to a composition comprising A, B, and C, Innovator likely cannot exclude X1 from the market due to the difficulty in proving infringement, particularly based on the *Festo* presumption of estoppel if Innovator's original claim, describing carriers that encompassed more than C, was narrowed during prosecution to describe carrier C only.¹⁷⁵

The outcome, however, can be different if the claim is framed with a means-plus-function clause. Instead of claiming a composition comprising A, B, and C, Innovator can claim a composition comprising A, B, and a means for improving A's absorption. The infringement analysis for X1 will not depend on the doctrine of equivalents because a court will likely find that X1 *literally* infringes the patent on X, as long as Innovator can establish (1) that C1 is a structural equivalent of C, and (2) that C1 serves the identical function as C.¹⁷⁶ Thus, an easy change in claiming style can substantially improve the economic consequences for the Innovator.

With structural claiming of specific elements of a formulation, such as the drug product, a patent may be practically useless in protecting Innovator's interest. Innovator will likely lose the market for its drug-product formulation soon after the regulatory exclusivity ends. By contrast, with MPF claims, Innovator has a higher chance both of successfully defending a PIV challenge through asserting literal infringement by the challenger's bioequivalent formulation and of ultimately enjoying the full statutory patent term of the formulation patent. Therefore, in the current industry—one in which pharmaceutical patents are constantly challenged by generic

175. See *supra* Part II.C.

176. See *infra* Part III.C.2.

manufacturers and patent scope of drug-product formulations can be unduly restricted to the literal scope of the elements recited in the formulation—statutorily granted MPF claims may offer more adequate protection to the innovators. Such protection could then translate into enhanced financial incentives to continue R&D investment in new medicine.

C. Issues Anticipated for the Application of MPF Claims to Pharmaceutical Patents

The patent system is still in search of the optimal standard for identifying and construing MPF claims.¹⁷⁷ A number of issues have arisen during the application of § 112 ¶ 6 in other contexts.¹⁷⁸ Similar issues can be anticipated when incorporating MPF claims into pharmaceutical patents. The potential issues fall into three categories: (1) when to invoke § 112 ¶ 6, (2) whether an MPF claim is infringed by a particular product, and (3) whether an MPF claim is patentable over the prior art.

1. *When Is § 112 ¶ 6 Invoked?* The USPTO has provided the following three-point guideline on this threshold question:

Examiners will apply § 112, ¶ 6 to a claim limitation that meets the following conditions: (1) The claim limitation uses the phrase “means for” or “step for” or a *non-structural term* that does not have a structural modifier; (2) the phrase “means for” or “step for” or the non-structural term recited in the claim is modified by functional language; and (3) the phrase “means for” or “step for” or the non-structural term recited in the claim is not modified by sufficient structure, material, or acts for achieving the specified function.¹⁷⁹

177. See Cyrill P. Rigamonti, *Conflicting Theories of Equivalence: 35 U.S.C. § 112, ¶ 6 in the Supreme Court and the Federal Circuit*, 40 IDEA 163, 164 (2000) (“[T]he Supreme Court and the Federal Circuit rely on two completely different theories when reading 35 U.S.C. § 112, para. 6.”); Triggs, *supra* note 31, at 31 (“More problematically, neither the U.S. Patent and Trademark Office (USPTO) nor the courts have developed a workable test to identify claims subject to the §112 ¶ 6 restriction, especially in a method claim.”).

178. See generally Bradley, *supra* note 31 (discussing the genesis of the equivalence standard under § 112 ¶ 6 and arguing that means-plus-function equivalence is no different than equivalence as defined in the doctrine of equivalents); Triggs, *supra* note 31, at 33–35 (detailing the numerous lines of cases in which courts have adopted different approaches to the application of § 112 ¶ 6 to method claims).

179. Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7162, 7167 (Feb. 9, 2011).

This guideline establishes that the trigger for the application of § 112 ¶ 6 lies in the claim language itself. A claim element is treated as a means-plus-function limitation if it is written in nonstructural terms, preferably as “means for” or as “step for,” with a functional statement but no structural description.¹⁸⁰ According to the statute, any structural modifier¹⁸¹ or structural description of the element could potential disqualify a patent applicant from invoking § 112 ¶ 6.¹⁸² The administration of this three-prong rule should be relatively straightforward with composition claims but might be more difficult with method claims.¹⁸³

During prosecution, the patent applicant is responsible for making clear whether a claim limitation invokes § 112 ¶ 6; failing to clarify this might result in a rejection of the claim for indefiniteness.¹⁸⁴ When an ambiguity of this nature is found in litigation, courts are to decide the applicability of § 112 ¶ 6 based on the judgment of “a person with ordinary skill in the relevant field.”¹⁸⁵

180. *Id.*

181. To determine whether a modifier denotes structure,

examiners should check whether: (1) [t]he specification provides a description sufficient to inform one of ordinary skill in the art that the term denotes structure; (2) general and subject matter specific dictionaries provide evidence that the term has achieved recognition as a noun denoting structure; and (3) the prior art provides evidence that the term has an art-recognized structure to perform the claimed function.

Id.

182. See 35 U.S.C. § 112 (2006) (“An element in a claim for a combination may be expressed as a means or step for performing a specified function *without the recital of structure, material, or acts in support thereof*” (emphasis added)), *amended by* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 4(c), 125 Stat. 284, 296 (2011); *see also* Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. at 7167 (“Examiners will apply § 112, ¶6 to a claim limitation . . . unless the non-structural term is (1) preceded by a structural modifier . . . or (2) modified by sufficient structure or material for achieving the claimed function.”).

183. See *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 848–49 (Fed. Cir. 1999) (Rader, J., concurring) (“[I]dentifying step-plus-function claims [is] inherently more problematic.”); Triggs, *supra* note 31, at 31 (“[N]either the U.S. Patent and Trademark Office (USPTO) nor the courts have developed a workable test to identify claims subject to the § 112 para. 6 restriction, especially in a method claim.”). Method claims are inherently more difficult partly because it is hard to distinguish whether a step of a method is expressed as a step for performing a specified function without the recital of any act in support of such function.

184. See Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. at 7167 (“When it is unclear whether a claim limitation invokes § 112, ¶ 6 or not, a rejection under § 112, ¶ 2 may be appropriate.”).

185. *Rowe Int’l Corp. v. Ecast, Inc.*, 586 F. Supp. 2d 924, 951 (N.D. Ill. 2008).

2. *Determining Infringement in Litigation.* Two types of infringement exist for any patent claim: literal infringement and infringement under the doctrine of equivalents.¹⁸⁶ Section 112 ¶ 6 provides a test for literal infringement, but not for infringement under the doctrine of equivalents.¹⁸⁷ Because the literal infringement analysis of MPF claims involves identification of structural “equivalents” of embodiments disclosed in the specification, confusion could result if MPF claims were subjected to an infringement analysis under the doctrine of equivalents.

In an ordinary literal-infringement analysis, courts only need to examine whether the accused product or process contains all structures or acts as literally provided in the claim elements. For MPF claims, because the claim language describes function instead of structure or an act, an additional step is needed to link the structure or act in the specification to the function described in the claim. Based on the language in the 1952 Act, the Federal Circuit has held that an accused product or process contains the element as described in a means-plus-function clause if (1) it contains a structure that is equivalent to the structure disclosed in the specification corresponding to the functional limitation, and (2) the equivalent structure performs the same function that is stated in the claim.¹⁸⁸ For example, in the previous hypothetical, if the patent for drug X claims a composition containing A, B, and C, which is a means for improving A’s absorption, then the generic drug X1 which contains A, B, and C1 literally infringes the patent if (1) C1 is a structural equivalent of C, and (2) C1 performs the same function as C in promoting A’s absorption.

The issue of infringement under the doctrine of equivalents is logically more difficult than the issue of direct infringement, and commentators have disagreed about whether and how the doctrine should apply to MPF claims.¹⁸⁹ In *WMS Gaming, Inc. v. International*

186. See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997) (“[A] product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is ‘equivalence’ between the elements of the accused product or process and the claimed elements of the patented invention.” (quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950))).

187. See 35 U.S.C. § 112 (stating that MPF claims “shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof”).

188. *Cortland Line Co. v. Orvis Co.*, 203 F.3d 1351, 1358 (Fed. Cir. 2000).

189. At least three different approaches have been proposed on this issue. Some scholars argue that § 112 ¶ 6 only concerns literal infringement; therefore, the doctrine of equivalents

Game Technology,¹⁹⁰ the Federal Circuit provided an in-depth analysis of this issue and held that the doctrine of equivalents does apply to MPF claims.¹⁹¹ In dealing with the difficult issue of “equivalents of equivalent,” the court distinguished between the literal scope and the equivalent scope of an MPF claim using two related concepts: structural equivalents and functional equivalents.¹⁹² The court reasoned that the literal scope of an MPF claim covers devices containing a structural equivalent that serves the identical function as stated in the claim; and the doctrine of equivalents extends the claim to cover devices employing a structural equivalent that serves an equivalent, but not identical, function.¹⁹³ Under this analysis, if carrier C1 has an equivalent, but not identical, function to that of C, drug X1 could infringe the patent claim on X under the doctrine of equivalents, but not literally. This approach is most consistent with the two-step infringement analysis under *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*¹⁹⁴ In addition, it promotes equity and efficacy of the patent system.¹⁹⁵

3. *Patentability Issues During Prosecution.* To procure a patent containing an MPF claim, the applicant first needs to convince the USPTO that her invention is patentable. Similar patentability issues might arise during litigation as well, when courts examine the

should be precluded after a finding of no literal infringement. Chad S.C. Stover, Comment, *Deciphering Means-Plus-Function Claim Limitation Infringement Under § 112, Paragraph 6: Finding Certainty in the Uncertain Case Law*, 3 N.C. J.L. & TECH. 101, 107 (2001). Others believe that “the means-plus-function clause should be accorded the scope of equivalence allowed by the traditional doctrine of equivalents,” basically eliminating the difference between literal infringement and equivalent infringement for § 112 ¶ 6 claims. See, e.g., Bradley, *supra* note 31, at 16 (noting that this interpretation “would eliminate . . . the double standard of equivalence”). Finally, some suggest that if a § 112 ¶ 6 claim is not literally infringed only because the structural equivalent in the accused device performs substantially the same—but not exactly the same—function as the claim provides, it may still be found to have been infringed under the doctrine of equivalents. See, e.g., John N. Kandara, Note, *Application of the Doctrine of Equivalents to Means Plus Function Claims: WMS Gaming Inc. v. International Game Technology*, 50 DUKE L.J. 887, 905–15 (2000) (arguing, *inter alia*, that this interpretation promotes fundamental fairness).

190. WMS Gaming, Inc. v. Int’l Game Tech., 184 F.3d 1339 (Fed. Cir. 1999).

191. *Id.* at 1353–54.

192. See *id.* at 1353 (“[A]n accused device can infringe under the doctrine of equivalents without infringing literally under 35 U.S.C. § 112, ¶ 6 because the doctrine only requires substantially the same function, not identity of function as in section 112, ¶ 6.”).

193. *Id.*

194. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17 (1997). For a discussion of this two-step analysis, see *supra* notes 109–110 and accompanying text.

195. Kandara, *supra* note 189, at 889.

challenged patent under the same statutory criteria used by the patent examiner at the USPTO.¹⁹⁶ When MPF claims were first authorized by the 1952 Act, Federico stated that the second part of the § 112 ¶ 6 provision applied only in infringement analysis but not in patentability analysis.¹⁹⁷ Consequently, the USPTO did not engage in patentability analysis of MPF claims over the prior art for more than forty years. In 1994, the Federal Circuit finally held that § 112 ¶ 6 applies both to patentability examination during prosecution and to infringement or validity analysis during litigation in the landmark case *In re Donaldson Co.*¹⁹⁸ Because the patentability issues during prosecution were not even recognized for more than forty years, and because MPF claims remain barely explored in pharmaceutical patents, some challenging issues might arise during prosecution.

A claim can be unpatentable because of prior art if, in accord with its broadest reasonable construction, the claim is more likely than not (1) *anticipated* by prior art,¹⁹⁹ or (2) rendered *obvious* by prior art.²⁰⁰ The anticipation issue is relatively straightforward: “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.”²⁰¹ An MPF claim requires an additional inquiry to determine whether a functional element is present in the prior art. For this purpose, the USPTO has provided a three-part rule in the *Manual of Patent Examining Procedure*.²⁰² Similar to the infringement

196. See 35 U.S.C. §§ 101–103, 112 (2006) (detailing the criteria for patentability), *amended* by Leahy-Smith America Invents Act, Pub. L. No. 112-29, §§ 3(b)(1), (c), (n), 4(c), 125 Stat. 284, 285, 287, 293, 296 (2011). Significant differences, however, exist between evaluation of a claim during prosecution and litigation. During prosecution, the USPTO adopts the broadest reasonable construction of a patent application claim and must show that, more likely than not, the claim is not patentable. *In re Baxter Int’l, Inc.*, 678 F.3d 1357, 1360 (Fed. Cir. 2012). In litigation, owing to the presumption of validity of the patent, the alleged infringer is stuck with whatever claim construction comes out of the *Markman* hearing and then has the burden to show invalidity and/or unenforceability by clear and convincing evidence of the claim as so construed. *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1378 (Fed. Cir. 2005).

197. Federico, *supra* note 168, at 186–87.

198. *In re Donaldson Co.*, 16 F.3d 1189 (Fed. Cir. 1994).

199. See 35 U.S.C. § 102 (defining statutory novelty).

200. See *id.* § 103 (defining statutory obviousness). In general, this will be also true under the America Invents Act, except that the anticipatory prior art has a different definition with specific exceptions, and the § 103 analysis will be performed as of the effective filing date of the claimed invention and not at the date of invention. Leahy-Smith America Invents Act, § 3(b)–(c), 125 Stat. at 2855–78 (to be codified at 35 U.S.C. §§ 102–103).

201. *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987).

202. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2183 (9th rev. 2012), *available at* <http://www.uspto.gov/web/offices/pac/mpep/mpep-2100.pdf>.

analysis, the functional element is found in prior art when an “equivalent” is identified—that is, when “the examiner finds that a prior art element (A) performs the function specified in the claim, (B) is not excluded by any explicit definition provided in the specification for an equivalent, and (C) is an equivalent of the means-(or step)-plus-function limitation.”²⁰³

The obviousness issue for MPF claims, however, is more complicated and lacks regulatory guidance. Nonetheless, developing a test for obviousness for MPF claims requires no more than following the well-established standard with some consideration for the special nature of MPF claims. In general, an invention is unpatentable if the differences between it and the prior art “are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.”²⁰⁴ Importantly, one inquiry to make is “whether the improvement is more than the predictable use of prior-art elements according to their *established functions*.”²⁰⁵ Accordingly, with respect to an MPF claim, the threshold question in determining obviousness should be whether the prior-art element was known to carry the identical or equivalent function as provided in the claim at the time of invention. If the function was unknown, then the invention is nonobvious; if the function was known, then the inquiry should be whether it is obvious to those skilled in the art to combine this prior art with other references to arrive at the claimed invention.²⁰⁶

In the previous hypothetical, assume Innovator is pursuing a patent application with a claim of composition comprising A, B, and C, which is a means to improve the absorption of A. The specification provides a description of C and its function in improving A’s absorption. Further assume that A, B, and C are all found in three separate prior-art references, and the question is whether the prior art, combined, renders the claimed invention obvious. The threshold inquiry should be whether C was known to improve A’s absorption at the time of invention.²⁰⁷ If not, then the invention is not obvious, and

203. *Id.*

204. 35 U.S.C. § 103(a).

205. KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007) (emphasis added).

206. See *supra* note 204 and accompanying text.

207. The America Invents Act provides that U.S. patents with claims having an effective filing date on or after March 16, 2013, will be generally granted to the “first-inventor-to-file.” Leahy-Smith America Invents Act, § 3(n), 125 Stat. at 293. Under the new law, the proper

that should be the end of the inquiry. Only when C was known for this function should the analysis proceed to the next question of whether it is obvious to a person skilled in the art to combine the three references. If yes, then arguably the *prima facie* obviousness of the claim is established.

In summary, MPF claims, as authorized by the 1952 Act, have great potential applications in pharmaceutical patents. These claims can add clarity to a patent and can provide the patent with a broader literal scope to confer effective protection. Due to the historical lack of use of MPF claims in composition patents, the law is still evolving and a number of issues will need to be resolved in the future. Nonetheless, prosecutors for drug patents should consider using MPF claims for the reasons described here.

CONCLUSION

The industrial trend of cutting R&D budgets and the drying up of new product pipelines in innovative firms signify diminished future innovation, which means not only fewer life-saving drugs for the public but also a loss for local and national economies. From a broader perspective, the lack of sufficient financial incentives is by no means the only reason behind the shortage of pharmaceutical innovation. Solutions need to be found to reduce the high cost of drug development, and new models of R&D are needed to improve the efficiency of the system that frames innovation within the industry. Nonetheless, the patent system has traditionally played an indispensable role in incentivizing pharmaceutical innovation, and the current lack of investment suggests an inadequacy of the system that must be cured.

Since the enactment of the Hatch-Waxman Act, PIV challenges have become pervasive and scholars have criticized their negative effect on innovative firms, especially in the form of shortened effective lives for patents.²⁰⁸ Many have proposed an extension of the regulatory-exclusivity period as a solution.²⁰⁹ The other dimension of

inquiry will be whether C was known to improve A's absorption at the time of the effective filing date of the claimed invention. *See supra* note 200.

208. *See* Higgins & Graham, *supra* note 4, at 371 ("These [PIV] challenges . . . shorten patent life."); Wilson, *supra* note 18, at 506 ("[T]he Drug Price Competition and Patent Term Restoration Act of 1984 actually results in shorter effective patent terms." (footnote omitted)).

209. *See, e.g.*, Grabowski & Moe, *supra* note 20, at 88 (proposing "a longer exclusivity time for new drugs as well as biologicals"); Gerald J. Mossinghoff, *supra* note 18, at 192 (proposing "chang[ing] the five-year data exclusivity to ten years in accordance with international

the issue—inadequate patent scope—should not be ignored because it greatly exacerbates the problems created by the prevalence of PIV challenges. Under the current jurisprudence regarding the doctrine of equivalents, many patent claims are limited to their literal scope and are therefore easily designed around and incapable of providing effective protection to innovators to stimulate investment. Therefore, MPF claims, which can provide a more appropriate scope of protection under the restrictive application of the doctrine of equivalents, are well-placed for consideration as an efficient solution.

standards”); Alastair J.J. Wood, *A Proposal for Radical Changes in the Drug-Approval Process*, 355 NEW ENG. J. MED. 618, 620 (2006) (“[A]n extended period of exclusivity should be offered to drug manufacturers . . .”).